Appl. No. 10/734,381
Atty.Docket No. 7858MRR
Amdt. Dated September 11, 2006
Reply to First Office Action Dated March 20, 2006
Customer Number 27752

REMARKS

Claim Status

Applicants confirm the election with traverse of triclosan as the single species of additional oral care agent to prosecute in the application, in response to the restriction requirement issued by the Examiner by telephone on March 3, 2006. Claims 7 to 9 which are drawn to nonelected species are withdrawn at this time.

Claims 1 to 3 are amended to replace the expression "polymeric mineral surface active agent" by copolymer or cotelomer, in response to the objection to the expression as indefinite. Support for this amendment may be found in original Claims 2 and 3 and in the Specification at Pages 6-7 in the paragraphs discussing examples of phosphonate containing copolymers or cotelomers.

Claim 1 is further amended to more specifically define the present claimed method as involving the administration of an oral care composition comprising such phosphonate containing copolymer or cotelomer and fluoride to provide enhanced fluoride incorporation into and remineralization of teeth.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Claims 1 to 6 and 10 are under consideration. Claims 7 to 9 are withdrawn.

Restriction Requirement

The restriction requirement with respect to the species of additional oral care agents recited in Claims 5 to 9 is respectfully traversed.

The major reason for restriction requirements is the unduly burdensome effect to the Examiner of searching the art for a variety of distinct species. In this instance, searching the art for the alleged distinct species of materials would involve the same body of art, being specifically art classified under Class 424, Subclass 49 and indented Subclasses 50 through 58, under 424/49. These art classes include compositions and methods involved primarily in the normal hygiene of the oral cavity regardless of product form or whether they contain different active components. Thus, subclass 424/49 would include compositions that contain ingredients having activity in killing micro-organisms or in the treatment or prevention of

specific oral conditions or malfunctions. As indicated in the Classification Definitions, indented subclasses 50 to 58 are set out to include significant kinds of ingredients, since dentifrices and mouthwashes are generally compounded with a plurality of ingredients. For example, subclasses 424/52 and 424/57 would include compositions for mouth care containing respectively, a fluorine containing compound and a phosphate compound. Applicants respectfully submit that it would not place a serious burden on the Examiner to search these classes for compositions comprising various species of antimicrobial agents, desensitizing agents, remineralization agents or whitening agents as recited in Claims 6 to 9. Further, Applicants point out that the main claim is directed to the combination of a phosphonate containing copolymer and fluoride for enhanced fluoride incorporation into teeth. The restriction with respect to the species of additional oral care agent would not be meaningful with respect to the broadest claim. As indicated in the MPEP § 803, if the search and examination of an entire application can be made without serious burden, the application must be examined on the merits, even though it may include claims to independent or distinct inventions. The PTO examination would be simplified and duplicate searching eliminated by pursuing one as opposed to two or more applications.

Applicants respectfully request withdrawal of the restriction requirement and rejoining of dependent claims 7 to 9 in the application.

Rejection Under 35 USC 112, Second Paragraph

The Office Action states that Claims 1-6 and 10 are rejected under 35 USC § 112, 2nd Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

It is respectfully submitted that the claims as amended are in full compliance of the requirements of 35 U.S.C. § 112, 2nd Paragraph and the rejection should be withdrawn.

The term "polymeric mineral surface active agent" considered as indefinite has been replaced with copolymer or cotelomer, which fully describe the claimed polymeric materials containing phosphonate groups.

Claims Rejection Under 35 U.S.C. §102(b)

Claims 1-6 and 10 have been rejected under 35 USC §102(b) as being anticipated by Gaffar et al. (U.S. 5,032,386). It is contended that Gaffar discloses antiplaque dentifrices comprising (1) antiplaque agents such as triclosan, (2) polyphosphonates having affinity for tooth surfaces and (3) fluorine compounds such as sodium fluoride. Further, it is contended that since Gaffar's compositions provide a continuous film over teeth surfaces following application to prevent bacterial attachment to tooth surfaces, it is expected they would also provide enhanced fluoride incorporation into and remineralization of a subject's teeth.

Applicants respectfully traverse the Examiner's rejection of the claims under 35 §102(b) and submit that the claimed method to provide enhanced fluoride incorporation into and remineralization of the subject's teeth is novel from Gaffar.

It is respectfully submitted that Gaffar has no disclosure of the present claimed phosphonate containing copolymers or cotelomers that have the activity of enhancing fluoridation and remineralization of teeth. As demonstrated in the studies conducted by Applicants, incorporation of the present phosphonate copolymers in fluoride dentifrices results in increased fluoride uptake. Thus for example, as shown in Table 1 in the Specification, a composition with 1100 ppm fluoride and 2.5% diphosphonate/acrylate copolymer provides nearly the same fluoride uptake as a composition containing 2800 ppm fluoride and significantly greater fluoride uptake (70% increase) compared to a composition with 1100 ppm fluoride but no phosphonate polymer. The present phosphonate containing polymeric materials are also characterized by being hydrophilic and having the activity to deposit on teeth and increase hydrophilic character of teeth surfaces. By contrast, Gaffar discloses polyphosphonates, such as poly (vinyl phosphonic acid), poly (beta styrene phosphonic acid and poly (butene-4,4-diphosphonate) which are hydrophobic, rather than hydrophilic. Gaffar's polyphosphonates are intended to function as antibacterial-enhancing agent (AEA), specifically to enhance delivery of noncationic water-insoluble (i.e., hydrophobic) antibacterials such as triclosan to oral surfaces. Thus Gaffar's AEA materials necessarily contain delivery enhancing groups and retention-enhancing groups. The delivery enhancing group such as phosphonate serves to attach the AEA to the tooth surface. The retention enhancing group serves to bond or attach the noncationic antibacterial agent to the AEA and is hydrophobic. The AEA would carry with it the noncationic antibacterial agent to

the tooth surface upon deposition. For example, a preferred AEA is poly (beta styrene phosphonic acid), which contains phosphonic group as the delivery enhancing group and styrene as the hydrophobic retention-enhancing group. The hydrophobic group is necessary to bond or attach the noncationic water-insoluble antibacterial agent, which is also hydrophobic. Attention is directed to the following teaching in Gaffar at Column 6 regarding the hydrophobic nature of the AEA material.

> *The organic retention-enhancing group, generally hydrophobic, attaches or otherwise bonds the antibacterial agent to the AEA, thereby promoting retention of the antibacterial agent to the AEA and indirectly on the oral surfaces. In some instances, attachment of the antibacterial agent occurs through physical entrapment thereof by the AEA, especially when the AEA is a cross-linked polymer, the structure of which inherently provides increased sites for such entrapment. The presence of a higher molecular weight, more hydrophobic cross-linking moiety in the cross-linked polymer still further promotes the physical entrapment of the antibacterial agent to or by the cross-linked AEA polymer.*

Gaffar also teaches that other phosphonate copolymers such as disclosed in EPO 0321233 may be employed in the referenced compositions; however, Gaffar also specifies that such copolymers must contain or be modified to contain the above-defined hydrophobic retention-enhancing agents. (See Column 8, lines 1-3 of the patent.) Polymers that contain or are modified to contain Gaffar's hydrophobic retention-enhancing groups would be hydrophobic, rather than hydrophilic.

Therefore, Gaffar has no teaching of the present phosphonate copolymers, and definitely no teaching that the referenced phosphonate polymers would even attach fluoride and deliver it to the tooth surface and thereby increase fluoridation and remineralization of teeth. The rejection under 35 USC §102(b) in view of Gaffar should be withdrawn.

Double Patenting Rejection

Claims 1-6 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4 of commonly-assigned copending Application No. 10/737,425 in view of Gaffar et al.

In the interest of advancing prosecution of this case, Applicants will file a terminal disclaimer upon indication of allowance, which should overcome the double patenting rejection.

CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied reference. In view of the foregoing, reconsideration of this application, entry of the amendments presented, withdrawal of the restriction requirement and rejoining of the withdrawn claims, withdrawal of the rejections under 35 U.S.C. § 112, 2nd Paragraph and §102(b) and allowance of all claims are respectfully requested.

Respectfully submitted,

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